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Size 3.75 x 8.5 inches (95.25mm x 215.9 mm)

Medtronic

CARDIOBLATE® BP2

Surgical Ablation Device

60831

Directions for Use

! USA **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

Explanation of symbols on package labeling

Refer to the device labeling to see which symbols apply to this product

PYROGEN	Nonpyrogenic
STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Reuse
	Use By
! USA	For US Audiences Only
	Quantity
	Open Here
	Attention, See Instructions for Use
	Package Contents
LOT	Lot Number
	Upper Limit of Temperature

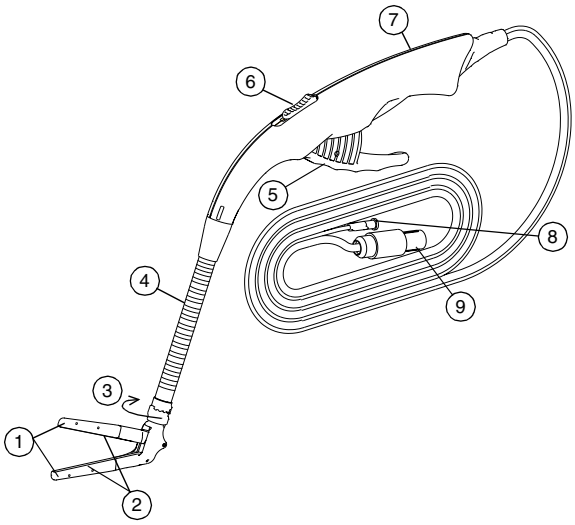

Figure 1.

Product Features

1. Adjustable parallel jaws, 7 cm (2.76 in) in length
2. Seven cm (2.76 in) electrodes with embedded weeping polymer, 5 cm (1.97 in) of which is malleable
3. 300° rotation of jaw assembly
4. Flexible neck
5. Trigger
6. Trigger lock with raised thumb slide
7. Molded handle
8. Saline fluid delivery tubing 304.8 cm (10 ft) in length with a female luer for connection to standard IV tubing systems
9. Electrical cable 304.8 cm (10 ft) in length that terminates into a multi-pin connector

Directions for Use

Cardioblate® BP2 Surgical Ablation Device

Model

60831

Description

The Cardioblate® BP2 Surgical Ablation Device is a hand held, single use, bipolar, radiofrequency ablation device for use in cardiac surgery. It has a saline irrigation system to deliver fluid at the contact point between the tissue and electrode to cool the tissue during radiofrequency energy delivery. The device is intended for intermittent operation.

Sterile, Nonpyrogenic, Disposable, Single use only.

Indications

This device is intended to ablate soft tissue during general surgery using radiofrequency energy.

Contraindications

The Cardioblate® BP2 Surgical Ablation Device should not be used for:

- Patients that have active endocarditis at time of surgery.
- Ablation in a pool of blood (e.g., through a purse string suture on a beating heart). Effects of this type of ablation are unknown.

Potential Complications

Possible complications related to the ablation of cardiac tissue in combination with open heart surgery are:

- Tissue perforation.
- Extension of extracorporeal bypass.
- Perioperative heart rhythm disturbances (atrial and/or ventricular).
- Postoperative embolic complications.
- Pericardial effusion or tamponade.
- Injury to the great vessels.
- Valve leaflet damage.
- Conduction disturbances (SA/AV node).
- Acute ischemic myocardial event.

Warnings

Do not activate device if saline is not flowing freely. The cooling of the outer tissue prevents the charring and tissue desiccation that may occur when applying radiofrequency energy without irrigation.

The device may be damaged before or during the procedure by improper handling or other intervening acts. If damaged, the device may fail to function properly, and may result in the following medical complications including, but not limited to:

- Damage to the physiological conduction system.
- Peripheral tissue ablation due to breach of insulation covering.

Device shall be removed from the patient during defibrillation.

No representation or warranty is made that failure or cessation of function of the device will not result in an adverse event, or that medical complications (including perforation of cardiac tissue) will not follow the procedure, or that the use of the device will in all cases restore adequate cardiac function.

Precautions

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Proper surgical procedures and techniques are necessarily the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of any procedure based on his or her own medical training and experience, and the type of surgical procedure.

Patient and procedure selection is solely a medical responsibility and the outcome is dependent on many variables including patient pathology, surgical and perfusion procedures.

Use caution to avoid trauma to tissues not within the target area of ablation.

Purge air from system to ensure saline fluid flows from the electrodes during use.

Separation of electrodes from tissue contact during activation will result in a high impedance shutdown placing generator power condition to “OFF.” Placing electrodes in direct contact during radiofrequency energy activation results in a low impedance shut down and places the generator power condition to “OFF.” In both situations, three short audible alarm “beeps” will be heard. Refer to the Medtronic Cardioblate® radiofrequency generator technical manual for reset instructions.

Maximum storage temperature: 40°C (104°F).

This device is designed and intended for single use only. DO NOT ATTEMPT TO REUSE AN ABLATION DEVICE. Multiple uses can result in the occlusion of the irrigation openings and affect the device’s performance. To prevent this from occurring, the generator has the capability to detect previously used ablation devices and will not allow their reuse.

It is the responsibility of the user to dispose of this device in accordance with local regulations.

Adverse Effects

None known.

Connections to External Devices

Bipolar Ablation Device

1. Connection to the Medtronic Cardioblate® generator is as follows:
   a. Position the multi-pin connector of the bipolar device so the alignment indicator matches the generator port indicator.
   b. Insert the multi-pin connector of the bipolar device into the device port on the front of the generator until it locks in place. Do not force the connection.

   Note: If additional devices are to be used, refer to their specific directions for use “Connections to External Devices.”

   Note: Connect to RF Generators (Only IEC / EN 60601-1 Type CF) with the following specifications:

RF power output setpoint/limit (Transmurality Mode)	Range: 25 to 40 W (automatically varying)
RF power output frequency	484.2 kHz ± 1%
Maximum RF voltage, between electrodes	159 Vrms

2. Sterile normal saline, commercially available pressure cuff, and IV tubing set are required for use with the bipolar device. These are not included with the Cardioblate BP2 Surgical Ablation Device.

Directions for Use

1. Inspect the package and device to ensure the expiration date has not passed and damage has not occurred to the device during shipping and handling. Do not use the device if the packaging or device is damaged or if the expiration date has lapsed. Open the package and transfer the device onto the sterile field utilizing aseptic technique.
2. Uncoil both the saline delivery tubing and the electrical cable carefully to avoid kinking and tangling.
3. Attach the saline delivery tubing female luer connector to an IV tubing set and 1000 mL bag of sterile normal saline. (0.9 normal saline is recommended because it provides a low impedance pathway for the radiofrequency energy to the tissue.)

4. If both a bipolar and monopolar device are being used, remove the sterile caps from the “Y” connector (Model 10004D) provided and attach the female luer of both devices. Then insert the IV line into the “Y” connector.

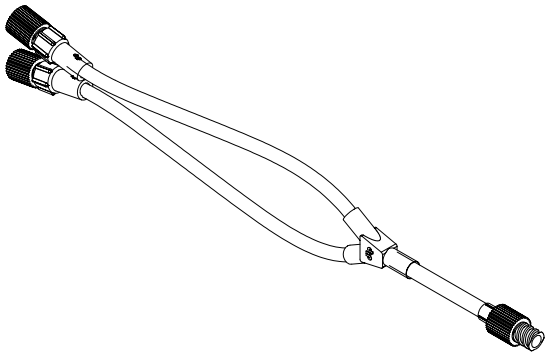

Figure 2.

5. Insert 1000 mL 0.9 normal saline into commercially available pressure cuff and inflate to between 150 mm Hg and 300 mm Hg.
6. Open the IV line and squeeze the trigger to purge the system of air until fluid is seen coming from the electrodes on the bipolar device. Release the trigger to stop IV flow.

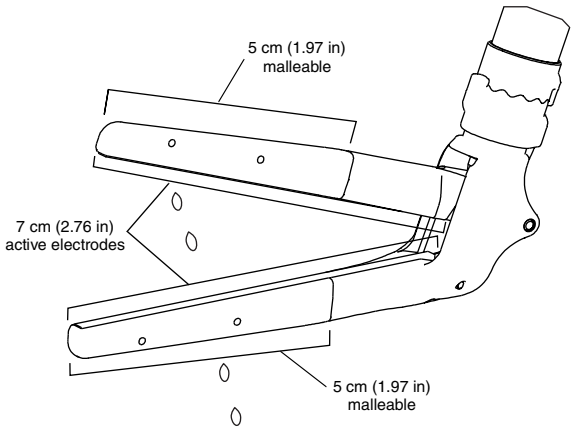

Figure 3.

7.
   a. Attach the bipolar electrical cable to the generator per instructions outlined in the “Connections to External Devices” listed above.
   b. Shape the electrodes as required for the targeted tissue. Engage the lock and squeeze the trigger to bring the electrodes together. Grip the electrodes with both hands to shape them. Care should be taken to ensure the electrodes are as parallel as possible. If the electrodes are out of alignment greater than 4 mm, the ability of the device to create a transmural lesion across the entire electrode length may be affected.
   c. Release the lock by moving it backward and open the electrodes. Use the flexible neck and 300° roll to assist in positioning the electrodes on the targeted tissue. Once the electrodes are correctly positioned, engage the lock and squeeze the trigger to bring the electrodes in full contact with the tissue. The lock must be engaged to ensure accurate transmurality readings.
   d. Confirm the generator selector is placed on the bipolar device.
8. Prior to tissue ablation:

a. Squeeze the trigger and make certain that saline is flowing freely out of the electrodes. Continuous flow of saline is necessary during ablation to cool the outer tissue. The cooling of the outer tissue prevents charring and tissue desiccation and allows radiofrequency energy to be delivered deeper into the tissue to more effectively create transmural lesions.

   Note: While irrigation increases the effectiveness of radiofrequency ablation, ablating in a pool of fluid can have a detrimental effect. Radiofrequency energy can shunt between the two electrodes and the transmurality algorithm may be less effective. Suctioning of excessive fluid at the ablation site is recommended to prevent this from occurring.

b. When using a bipolar device, the radiofrequency ablation generator will default to the “TRANSMURALITY” control mode.

c. In the “TRANSMURALITY” mode, all generator parameters will be automatically adjusted.

9. The current is activated in the device using the RF energy button or the foot switch provided with the Medtronic radiofrequency generator. The current flows between the electrodes.

Table 1. Anticipated Energy Delivery at Various Tissue Thicknesses

Tissue Thickness (7 cm length)	Energy Delivered (W.s)
1 mm	439±40
3 mm	505±25
5 mm	557±28

10. The lesion becomes visible by a white coloration on the tissue. In “TRANSMURALITY” control mode, the generator will emit a solid tone once a transmural lesion is created. This is the indication to the surgeon to stop ablating by releasing the foot switch or pressing the RF energy power button on the generator.

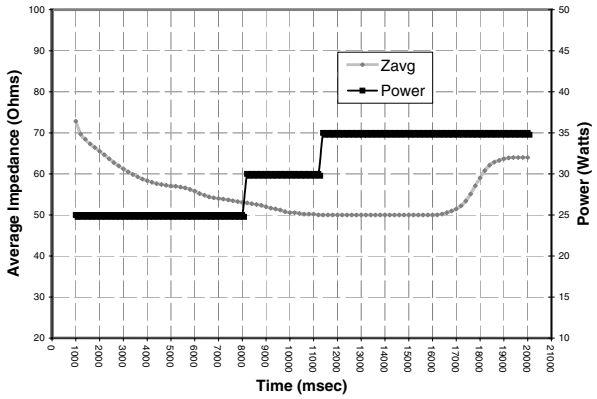

Figure 4. *Typical Tissue Impedance Values with Corresponding Power Levels. (Approximate total energy delivered 570 W.s)*

11. Ablating beyond recommended ablation times may result in tissue perforation.
12. Upon completion of the surgical procedure, disconnect the device from the generator and discard.

Disclaimer of Warranty

ALTHOUGH THE CARDIOBLATE® BP2 SURGICAL ABLATION DEVICE, HEREAFTER REFERRED TO AS "PRODUCT" HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, MEDTRONIC HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS USED. MEDTRONIC, THEREFORE DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MEDTRONIC SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND MEDTRONIC TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

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